January 29, 2004

The Honorable Mark B. McClellan, M.D., Ph.D.
Commissioner
U.S. Food and Drug Administration
Rockville, MD 20687

Dear Dr. McClellan:

I am writing to you regarding the findings of a report that I released today regarding FDA enforcement efforts. This report indicates that in 2003 there was a continuing decline in FDA's enforcement of regulations prohibiting false or misleading advertisements.

I first wrote to FDA on the subject of false and misleading advertising in October 2002.[1] My concerns at the time were that FDA enforcement of drug advertising regulations had declined considerably, and that when FDA did take actions to restrict false or misleading advertisements, these actions often did not take place until after advertisements had been running for months. My letter was soon followed by a GAO investigation of FDA oversight of direct-to-consumer advertising, which raised similar concerns.[2]

Your response to my letter and to the findings of the GAO report promised improved performance. First, you indicated that although the number of letters sent by FDA had declined, the number of enforcement actions would be expected to increase, and that "firms that commit repeated violations will face a much stronger basis for further enforcement actions."[3] You also stated that FDA would decrease the delays in responding to false or misleading advertisements.[4] And you indicated that the FDA was working on new guidance to assist manufacturers in

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[1] Letter from Rep. Henry A. Waxman to the Honorable Tommy G. Thompson (Oct. 1, 2002).

[2] GAO, *Prescription Drugs: FDA Oversight of Direct-to-Consumer Advertising Has Limitations* (Oct. 2002) (GAO-03-177).

[3] Letter from FDA Commisioner Mark B. McClellan to Rep. Henry A. Waxman (Mar. 31, 2003).

[4] *Id.*

complying with provisions barring false or misleading advertising.[5] It now appears that FDA has not succeeded in any of these three areas.

The report released today finds that:

- FDA enforcement of provisions barring false and misleading advertisements continued to decline in 2003. In total, the number of enforcement actions initiated by FDA in response to false or misleading advertisements was 75% lower than the number initiated during the last years of the Clinton Administration. In all of 2003, FDA sent only 24 letters in response to false or misleading advertisements by drug manufacturers.

- FDA's response to false or misleading advertisements was not timely, and delays increased. In cases where FDA did send letters in response to false or misleading advertisements in 2003, the average delay between ad placement and FDA citation in 2003 was 177 days — almost six months. This is a significant increase in delay compared to 2002. In one case, FDA did not send a "warning" letter until over one year after the suspect advertisement first appeared.

- The few actions taken by FDA have little deterrent effect. The enforcement actions that FDA took in 2003 were restricted to sending letters to drug manufacturers warning the manufacturer to cease using an advertisement. Although FDA has the authority to take stronger actions with more deterrent effect, such as bringing a court action seeking an injunction or ultimately fines, FDA initiated no such actions in 2003.

I request that you submit information regarding the continuing decline in FDA enforcement activities. Specifically, I request that you provide me the following:

1. An explanation of why FDA has not taken judicial enforcement actions against repeat violators of provisions barring false and misleading promotions.

2. A description of the circumstances under which FDA would take judicial enforcement actions against drug manufacturers who violate provisions against false and misleading promotions.

3. An explanation of why the delays in responding to false or misleading promotions have increased in the last year, and a detailed explanation of your efforts to reduce these delays.

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[5] *New Guidance for DTC Ads Expected by Year's End*, Wall Street Journal (Aug. 29, 2003).

4. A description of the status and content of the new guidelines that FDA indicated would be released in 2003.

5. A list of any contacts you or your staff have had with drug manufacturers in developing these new guidelines.

If you have any questions regarding this request, my staff contact is Brian Cohen, at (202) 225-5051.

Sincerely,

Henry A. Waxman

Henry A. Waxman
Ranking Minority Member